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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/252,691	02/18/99	WEINSTOCK K	107196.135

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EXAMINER	
PORTNER, V	
ART UNIT	**PAPER NUMBER**
1645	19

DATE MAILED: 02/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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Office Action Summary

Application No.	Applicant(s)
09/252,691	Weinstock et al
Examiner	**Group Art Unit**
Portner	1645

☒ Responsive to communication(s) filed on *Nov 13, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-28* is/are pending in the application.

Of the above, claim(s) *14-28* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-13* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-28* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Claims 1-28 are pending, claims 1,5,9 and 10 have been amended.

Claims 14-28 stand withdrawn from consideration.

Claims 1-13 are under consideration.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Rejections Withdrawn

2. Claims 1-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1,5,9 and 10 rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, credible and substantial asserted utility or a well established utility for the elected invention of SEQ ID NO 7056 for reasons of record in paper number 14.

4. Claims 1,5,9 and 10 rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible and substantial asserted utility or a

well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for reasons of record in paper number 14.

Rejections Maintained

5. Claims 2-4,6-8,11-13 rejected under 35 U.S.C. 101 because the claimed invention is not supported by a specific, credible and substantial asserted utility or a well established utility for the elected invention of SEQ ID NO 7056 for reasons of record in paper number 14.

6. Claims 2-4,6-8,11-13 rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, credible and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention for reasons of record in paper number 14, paragraphs 10 and 11.

7. Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for probes and primers, the instant specification , does not reasonably provide enablement for gene therapy using the elected SEQ ID NO 7056, amended claims recite nucleic acid sequence SEQ ID No 1394. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention

commensurate in scope with these claims for reasons of record in paper number 14, paragraphs 10 and 13.

8. Claims 1,5,10 rejected under 35 U.S.C. 102(b) as being anticipated by Haertl, R et al (1993) for reasons of record in paper number 14, paragraph 15.

9. Claims 1,5,10 rejected under 35 U.S.C. 102(b) as being anticipated by Matsutani, S et al (1991)for reasons of record in paper number 14, paragraph 16.

10. Claims 1,5,10 rejected under 35 U.S.C. 102(b) as being anticipated by Lambert-Zechovsky, N et al (1992)for reasons of record in paper number 14, paragraph 17

Response to Arguments

11. Applicant's arguments filed November 13, 2000 have been fully considered but they are not persuasive.

12. The rejections of claims 2-4,6-8,11-13 under 35 U.S.C. 101 and 35 U.S.C. 112, first are argued to have utility because Enterobacter cloacae is a pathogen and the claimed nucleic acid is a open reading frame encoding a protein found in Enterobacter cloacae and states "Brian Stanton summarized the USPTO utility policies; he stated, that unlike for expressed sequence tags (i.e.,ESTs), utility exists for isolated DNA derived from organisms known to cause disease" and

from this statement asserts the utility of the polypeptide for preventing infection and to screen for agents which inhibit and prevent E.cloacae infections.

13. In response to Applicant's arguments, the examiner has withdrawn the Utility and Enablement rejections in part over claims 1,5,9 and 10, wherein the nucleic acid sequence would have utility for detection of the pathogen, but vectors, host cells and methods of making a polypeptide would not. The enablement previously conceded by the examiner, has been reconsidered, and while the vectors, host cells could be made, the resulting polypeptide could not be used as a vaccine or diagnostic composition as the protein (polypeptide) has not been taught in the instant specification to have either a specific, credible and substantial asserted utility or a well established utility. Utility of a polynucleotide ~~from could be used~~ could be in a method of detecting the complementary DNA and correlating it with the presence of this DNA with the pathogen in the sample. The encoded polypeptide was not defined to have utility based upon the polynucleotide by Brian ~~Staton~~ Stanton. The utility of a polypeptide produced by a pathogen differs from that of a polynucleotide in that a polypeptide by nature does not bind to the pathogen and therefore could not be used as a detection agent. The polypeptide would need to be one that would correlate with the presence of antibodies induced by the pathogen that are specific and diagnostic of infection. All proteins are not vaccine antigens and do not induce protective immune responses. Use of a polypeptide to induce an immune response to detect the polypeptide does not define a specific, credible and substantial asserted utility or a well established utility.

Protein based vaccines for Enterobacter cloacae have not been shown to be effective in preventing or treating infection, therefore DNA based vaccines that encode a protein would also not evidence enablement for the induction of a protective immune response. While polypeptides and proteins are known to be immunogenic, induction of a protective immune response is not predictable in the vaccine arts.

Upon consideration of the prior art, for any type of vaccine composition that comprises Enterobacter cloacae isolated antigen, none could be found that induced a protective immune response. Shryock et al (1987, abstract) was the only reference found by the examiner that taught an Enterobacter cloacae single antigen composition, albeit a lipopolysaccharide composition, that had been used to try and induce a protective immune response. The disclosure of Shryock showed that the lipopolysaccharide, a major bacterial surface antigen, did not induce a protective immune response. No isolated polypeptide or protein vaccine compositions that contain only single Enterobacter cloacae antigen were found in the prior art. No single antigen compositions for this pathogen that serve as effective vaccine compositions could be found in the prior art. The utility and enablement rejections are maintained for reasons of record.

14. The rejection of claims 11-13 under 35 U.S.C. 112, first paragraph, claims drawn to DNA based vaccines, wherein the nucleic acid is SEQ ID No 1394 is argued that the claimed compositions, in light of the guidance provided in the instant specification and the knowledge in

the art, would have been sufficient for an individual of skill in the art to make and use the claimed nucleic acids in the form of a vaccine.

15. In response to Applicant's arguments with respect to DNA based vaccines, it is the position of the examiner that while compositions containing a nucleic acid molecule could be formulated, their use as a vaccine composition is unpredictable. Stimulation of a protective immune response is unpredictable. The ability of a single polypeptide to induce an immune response that blocks a pathogenic bacteria from establishing colonization, infection and disease is not predictable. The nucleic acid claimed, encodes a hypothetical protein, with a putative function (see instant specification page 53, line 7 and Table 2). No evidence has been made of record that shows that the asserted characteristics of the encoded polypeptide would induce a protective immune response and prevent infection or treat infection upon challenge with a virulent strain of Enterobacter cloacae. No single protein based vaccines are known to prevent or treat Enterobacter cloacae, nor any nucleic acid vaccines that encode a protein or polypeptide known as well. If what Applicant wants to claim is a composition that comprises a diluent or carrier, such a composition would not be subject to a scope of enablement rejection. The rejection of claim 11-13 is maintained for reasons of record defined in paragraphs 10 and 13.

16. The rejection of claims 1,5,10 under 35 U.S.C. 102(b) as being anticipated by Haertl, R et al (1993) is argued as not disclosing the claimed SEQ ID NO 7056 and therefore does not disclose or render obvious the claimed invention.

17. In response to Applicant's arguments, it is the position of the examiner that the claimed isolated nucleic acid that comprises the claimed sequence reads on isolated Enterobacter cloacae chromosomal DNA. Haertl et al states that whole cell DNA was purified from Enterobacter cloacae (see page 128, col. 2, second line from the bottom). Bacteria only have a single chromosome and upon isolation of the chromosomal DNA from the cell, the isolated nucleic acid would comprise the coding regions for the polypeptides produced by E.cloacae. Applicant could obviate this rejection by amending the claims to recite closed language --consisting of--.

18. The rejection of claims 1,5,10 under 35 U.S.C. 102(b) as being anticipated by Matsutani, S et al is argued to only show the isolation and characterization of DNA fragments comprising a repetitive sequence.

19. In response to Applicant's arguments, it is the position of the examiner, that the claimed isolated nucleic acid that comprises the claimed sequence reads on isolated Enterobacter cloacae chromosomal DNA. Matsutani et al disclose isolated chromosomal DNA from Enterobacter cloacae (see page 7803, col. 1, paragraph 5). Bacteria only have a single chromosome and upon isolation of the chromosomal DNA from the cell, the isolated nucleic acid would comprise the coding regions for the polypeptides produced by E.cloacae. Applicant could obviate this rejection by amending the claims to recite closed language --consisting of--. The rejection is maintained for reasons of record in paper number 14, paragraph 16.

20. The rejection of claims 1,5,10 under 35 U.S.C. 102(b) as being anticipated by Lambert-Zechovsky, N et al (1992) is argued to only describe the restriction fragment length polymorphism analysis of five strains of E.cloacae DNA and does not teach or suggest an isolated nucleic acid sequence of at least eight nucleotides which can hybridize to SEQ ID NO 1394.

21. In response to Applicant's arguments, it is the position of the examiner, that an isolated nucleic acid that comprises the claimed sequence reads on E.cloacae isolated chromosomal DNA. The recitation of the claim limitations "at least 8" without an upper limit reads on chromosomal DNA. Lambert-Zechovsky et al discloses the isolation of total DNA was purified from Enterobacter cloacae (see page 31, col. 1, paragraph 2, lines 1-2). Bacteria only have a single chromosome and upon isolation of the chromosomal DNA from the cell, the isolated nucleic acid would.comprise the coding regions for the polypeptides produced by E.cloacae. Applicant could obviate this rejection by amending the claims to recite closed language --consisting of--. The rejection is maintained for reasons of record in paragraph 17.

New Grounds of Rejection

Claim Rejections - 35 U.S.C. § 112

22. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

23. Claims 1,5,9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,5,9 and 10 have been amended to recite both open and closed language through the claim limitations of 'comprising' and 'is'. This is confusing. Claim 1 defines the sequence to encode a polypeptide and is SEQ ID NO 1394. SEQ ID No 1394 is a nucleic acid sequence and therefore is not a polypeptide. Clarification of the claimed invention is requested .

Claim Rejections - 35 U.S.C. § 102

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a pat
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

25. Claims 5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Blattner et al (January 29, 1997 (EMBL record, see sequence alignments **AE000213 and AAC74219**) or Oshima et al (1996,EMBL sequence alignments **D90748 and BAA35957**).

Blattner et al or Oshima et al disclose an isolated nucleic acid molecule, wherein the molecule is DNA and encodes a polypeptide that shares 100% sequence identity over 52

consecutive amino acids. The encoded 52 amino acids would correspond to 156 nucleic acids held in common with SEQ ID NO 1394. The amino acid sequences were obtained from the encoding nucleic acid sequence (see sited result 1, "RP" lines that show that the amino acid sequence was obtained from the nucleic acid sequence.)

The disclosed nucleic acid comprises a nucleic acid sequences that encodes an E.cloacae polypeptide fragment that shares a polypeptide amino acid sequence. The nucleic acid sequence encodes a polypeptide of 207 amino acids that shares 86.4% sequence identity over the entire SEQ ID NO 1394. The nucleic acid encodes 185 of a total 217 amino acids to the claimed encoded polypeptide. 100% sequence identity exists over 185 amino acids, an additional 12 amino acids represent conservative substitutions into the sequence, leaving only 19 out of 217 amino acids that differ over the entire SEQ ID NO 7056 which is encoded by SEQ ID NO 1394.

The disclosed nucleic acid of Blattner or Oshima et al anticipate the now claimed invention (see sequence alignment).

This is a non-final rejection.

No claims are allowed.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner

can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.
Vgp
January 26, 2001

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2/2/01